

# In the United States Court of Federal Claims

## OFFICE OF SPECIAL MASTERS

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RICHARD BRANTLEY,	*	No. 18-1416V
	*	Special Master Christian J. Moran
Petitioner,	*	
v.	*	
	*	Filed: October 20, 2023
SECRETARY OF HEALTH	*	
AND HUMAN SERVICES,	*	
	*	
Respondent.	*	

\* \* \* \* \*

Edward Kraus, Kraus Law Group, LLC, for petitioner;  
Terrence Mangan and Camille Collett, United States Dep't of Justice, Washington,  
DC, for respondent

### **DECISION DENYING ENTITLEMENT TO COMPENSATION<sup>1</sup>**

Richard Brantley alleges that an influenza (“flu”) vaccine caused him to develop small fiber neuropathy. Each party retained a neurologist to offer opinions. The retained neurologists differed as to whether Mr. Brantley suffered small fiber neuropathy.

The evidence, as explained below, does not preponderate in favor of finding that Mr. Brantley suffered from small fiber neuropathy. Thus, Mr. Brantley is not entitled to compensation.

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<sup>1</sup> Because this Decision contains a reasoned explanation for the action taken in this case, it must be made publicly accessible and will be posted on the United States Court of Federal Claims’ website, and/or at <https://www.govinfo.gov/app/collection/uscourts/national/cofc>, in accordance with the E-Government Act of 2002. 44 U.S.C. § 3501 note (2018) (Federal Management and Promotion of Electronic Government Services). This means the Decision will be available to anyone with access to the internet. In accordance with Vaccine Rule 18(b), the parties have 14 days to identify and move to redact medical or other information, the disclosure of which would constitute an unwarranted invasion of privacy. Any changes will appear in the document posted on the website.

## **I. Chronology**<sup>2</sup>

Mr. Brantley was born in October 1973. In September 2015, he worked as a sheriff's deputy. Exhibit 3 at 19. He rarely drank water, preferring to drink Mountain Dew. Id. at 20. While he had some health problems before the vaccination, the Secretary has not contended that any pre-existing health problems affect his claim for compensation. See Resp't's Br.

### **A. Vaccination and Problems within Two Days**

Mr. Brantley received a flu vaccine on Friday, September 25, 2015. Exhibit 12 at 1-2.<sup>3</sup> Within approximately eight hours of this vaccination, Mr. Brantley developed a range of problems, including swelling at the vaccination sites, general malaise, diffuse myalgias, cold sweats, diarrhea, and nausea. Exhibit 1 at 40, 50; Exhibit 3 at 19; Exhibit 5 at 12.

Mr. Brantley did not eat or drink very much over the weekend. Exhibit 3 at 19. Two days after the vaccination, on Sunday, while working outside as a sheriff's deputy and wearing his boots and vest, Mr. Brantley became fatigued. Id. While driving, Mr. Brantley blacked out and crashed his car. Exhibit 3 at 19; Exhibit 1 at 40.

After this car accident, Mr. Brantley was taken to a local emergency room. His blood pressure was low: 80's over 50's. Exhibit 3 at 19. He received fluids intravenously and he felt better after receiving them. Id.

Despite Mr. Brantley's improvement, he was admitted to the hospital because, in part, of acute renal failure. By the next day, blood tests showed that his kidney function had returned to normal. See Exhibit 4 at 1-2.

The foregoing list of health problems does not affect Mr. Brantley's claim that a flu vaccine caused him to suffer a neurological problem. Although Mr. Brantley maintains that these symptoms correspond to an "innate immune response," Pet'r's Br. at 10, Mr. Brantley "does not claim that these initial

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<sup>2</sup> The parties do not differ significantly about Mr. Brantley's medical history. Thus, the events in his life are presented somewhat summarily. For a lengthier summary, see Pet'r's Br. at 1-9 and Resp't's Br. at 2-10.

<sup>3</sup> On this same day, Mr. Brantley also received a dose of the tetanus-diphtheria-acellular pertussis vaccine and the Pneumovax vaccine. Exhibit 12 at 1-2. However, Mr. Brantley's claim for compensation rests upon the flu vaccine. See Resp't's Br. at 18 n.6; Pet'r's Reply at 9. Mr. Brantley has brought a case based upon the Pneumovax vaccine in state court. See Pet'r's Status Rep., filed Jan. 13, 2020.

reactions necessarily played any role in his developing SFN.” Pet’r’s Reply at 9. Thus, although subsequent medical records refer to problems such as dehydration and syncope, those medical records are not recounted in this decision.

## **B. Neurologic Problems Starting Potentially on Day Three**

While Mr. Brantley was hospitalized, a neurologist (Dr. Vikas Pandey) evaluated him. Dr. Pandey memorialized a history in which Mr. Brantley recounted that during his admission he “developed some numbness in his left side of the back progressing down to the left leg.” Exhibit 3 at 22. Mr. Brantley told Dr. Pandey that “his left foot feels numb as if it has fallen asleep.” *Id.* Upon examination, Dr. Pandey detected that Mr. Brantley had some weakness (4/5) in his left hip flexor, left knee extensor, and left foot dorsal flexion. *Id.* at 23. Dr. Pandey also observed decreased sensation over the left lower extremity. Mr. Brantley’s reflexes were intact. *Id.*

Dr. Pandey suggested that Mr. Brantley was suffering from Guillain-Barré syndrome. Exhibit 3 at 23. He recommended additional testing. The result of a test for albuminocytologic dissociation led Dr. Pandey to conclude that Mr. Brantley was not suffering from Guillain-Barré syndrome. Exhibit 3 at 36.<sup>4</sup> When Mr. Brantley was discharged from the hospital on September 30, 2015, his diagnoses did not include Guillain-Barré syndrome. *See* Exhibit 3 at 34-36.

In the view of Dr. Tornatore, Mr. Brantley’s sensory symptoms began three days after the vaccination. Exhibit 41 at 2; *see also* Pet’r’s Br. at 10 (asserting that “on September 28, 2015, Mr. Brantley developed the first symptoms of what was later diagnosed as small fiber sensory neuropathy”); Pet’r’s Reply at 10-11.<sup>5</sup> However, the Secretary asserts that the development of Mr. Brantley’s sensory problems occurred “just two days after his September 25, 2015 vaccinations.” Resp’t’s Br. at 35. For the reasons explained below, determining the hour at which Mr. Brantley developed sensory symptoms is not necessary to resolve Mr. Brantley’s case. The more important point is that both parties recognize that the sensory symptoms differed from the constitutional problems for which Mr. Brantley was initially treated while hospitalized.

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<sup>4</sup> About a month later, another doctor also ruled out Guillain-Barré syndrome. Exhibit 2 at 7 (Dr. McPherson on Nov. 9, 2015).

<sup>5</sup> On page 11 of his reply, Mr. Brantley cited Exhibit 10 at 7. However, that evidence does not support the statement that Dr. Tornatore indicated that the sensory symptoms began three days after vaccination.

After being released from the hospital, Mr. Brantley was seen at various times for neurologic problems beginning with an appointment with his primary care physician, Dr. Coker. Exhibit 1 at 12-14 (Oct. 6, 2015). Dr. Coker referred Mr. Brantley to a neurosurgeon.

Mr. Brantley told the neurosurgeon (Trung Nguyen) that he had “pain on the left hip radiating down to the thigh and leg,” and “numbness of the foot.” Exhibit 1 at 6. Dr. Nguyen’s examination was normal except for detecting a hard knot at the left median basilic vein. Id. at 8.

Mr. Brantley visited a hospital clinic on October 27, 2015, where he was seen by a physician’s assistant, Kalee Kirk. Exhibit 1 at 2. Mr. Brantley stated that he had numbness and tingling in his left pinky and ring finger, and that it felt like needles were poking his hand. Id. Ms. Kirk’s physical examination produced normal results. Ms. Kirk diagnosed Mr. Brantley as suffering from a neuropathy and referred him to a neurologist. Id. at 4.

The next doctor whom Mr. Brantley saw was a physiatrist, Richard McPherson. Exhibit 2 at 7.<sup>6</sup> The history was more or less in accord with the information presented above. Mr. Brantley added that he had returned to full-time work at the sheriff’s office, although he was feeling 30% worse than his baseline. Id. at 2. Mr. Brantley complained of intermittent lower back pain, occasional radiating pain in his left buttock, intermittent numbness in his hands and in the tips of his great toes, stiffness, and cramping. Upon examination, Mr. Brantley’s gait and muscle strength were normal, but he had decreased light touch sensation at the tips of his toes. Id. at 5.

Dr. McPherson characterized Mr. Brantley as presenting a “somewhat atypical interesting case.” Exhibit 2 at 7. Dr. McPherson suggested that “[w]ith his motor vehicle trauma, the possibility of a low grade lumbar facetogenic pain component is in the differential,” and offered that Mr. Brantley’s “somewhat systemic initial symptoms and persisting intermittent paresthesias may be reflective of a[n] autoimmune response to his immunization.” Id. Dr. McPherson deferred the care of neurologic problems to a neurologist and recommended that Mr. Brantley discuss future immunizations with his primary care doctor.

The neurologist whom Mr. Brantley had seen earlier was Dr. Pandey and Mr. Brantley returned to see Dr. Pandey on December 8, 2015. Exhibit 10 at 27. Mr. Brantley informed Dr. Pandey that he was having daily headaches that

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<sup>6</sup> A duplicate appears as Exhibit 1 at 55.

sometimes caused blurry vision and mild nausea. Id. at 29. Other symptoms included numbness and pins and needles sensations in both big toes, and occasional left arm numbness that awakened him in the night. Id. He also was experiencing dry eyes and vision changes, muscle aches and weakness in both arms, back pain on his left side, fatigue, and depression. Id. On examination, Dr. Pandey identified decreased range of motion in the spine and lower back, decreased pinprick and vibration reflexes, and numbness. Id. He assessed Mr. Brantley as suffering from severe headaches with migrainous features and a medication overuse component, lumbar radiculopathy, and radial neuropathy. Id. at 30.

More than two months later, Mr. Brantley again saw Dr. Pandey. Mr. Brantley stated that he continued to have pain, numbness and tingling in his left leg, along with fatigue and continued daily headaches. Exhibit 10 at 25-26 (Feb. 24, 2016). Dr. Pandey prescribed a medication.<sup>7</sup> About five months later, Mr. Brantley again complained about headaches and Dr. Pandey continued the prescription. Exhibit 9 at 5 (July 26, 2016).

### **C. NCV, EMG, and Other Testing**

A nerve conduction (NCV) and electromyogram (EMG) were conducted by a neurologist, Sunil Thummala, on September 8, 2016. Exhibit 10 at 41-47. The EMG was overall normal. Id. at 41. The NCV suggested that Mr. Brantley might have a left ulnar neuropathy, which was likely compressive, and a left-sided carpal tunnel syndrome. Id. In addition, the sympathetic skin response on Mr. Brantley's left side "showed reduced amplitude," which was abnormal but not specific. Id.

Mr. Brantley had another MRI of his left shoulder on October 11, 2016. Exhibit 10 at 33-34. He saw Dr. Pandey because of pain and headaches on November 3, 2016. Exhibit 10 at 11-14. Dr. Pandey wrote a letter addressed "To Whom It May Concern" on November 7, 2016. Exhibit 11. Dr. Pandey stated that "[w]hile there can be no definitive proof, there is evidence in the medical literature that Mr. Brantley's symptoms can be post-vaccination reactions and may have been adverse effects directly related to the vaccinations received." Id.

Following the appointments in November 2016, Mr. Brantley did not receive medical attention for a period. Mr. Brantley attested that no treatment or

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<sup>7</sup> Dr. Pandey assessed Mr. Brantley as suffering from "Parsonage Turner syndrome" after his vaccination. Exhibit 7 at 7. However, Mr. Brantley has not sought compensation for Parsonage Turner syndrome.

satisfactory explanation for his symptoms existed. Exhibit 19 (affidavit, dated Sept. 12, 2018) at 3. During this time, he had pain and numbness, mostly on his left side. Id.

After nearly one year, Mr. Brantley returned to Dr. Thummala with a report of left upper and lower extremity pain and episodes of loss of consciousness. Exhibit 13 at 16-17 (Aug. 24, 2017). Mr. Brantley described his pain as ranging from burning to prickling to electric sensations. To learn more information about a possible neuropathy, Dr. Thummala ordered punch biopsies.

The punch biopsies were obtained from Mr. Brantley's skin on his left leg and foot on August 29, 2017. Exhibit 13 at 38-39. The samples were sent to Therapath Laboratories.<sup>8</sup> Therapath reported: "Skin with significantly reduced epidermal nerve fiber density, consistent with small fiber neuropathy" in the left thigh, calf, and foot. Id. at 39.

Upon return of the biopsy results from Therapath, Mr. Brantley saw Dr. Thummala again. Dr. Thummala recounted much of Mr. Brantley's history beginning with the vaccinations and memorialized the concern of Mr. Brantley that the vaccinations caused his problems. Exhibit 13 at 4 (Nov. 1, 2017). Dr. Thummala stated that he had originally seen Mr. Brantley for an EMG and nerve conduction study. More recently, Dr. Thummala had conducted a "punch biopsy of the skin that confirmed neuropathy in all three specimens we collected." Id. With respect to the vaccination, Dr. Thummala "emphasized to [Mr. Brantley] that it is a possibility, however, it is difficult to pinpoint." Id. at 5. Dr. Thummala assessed Mr. Brantley as having "Pain in lower limb – possible small fiber neuropathy." Id. at 4.

The November 1, 2017 appointment with Dr. Thummala essentially ends the list of relevant medical appointments. See Pet'r's Br. at 8-9; Resp't's Br. at 9-10. Mr. Brantley has continued to have multiple problems. See Exhibit 20 (affidavit regarding damages, filed Nov. 19, 2018) at 5.

## **II. Procedural History**

The course of this case in litigation is relatively straightforward. Mr. Brantley initiated the case by filing his petition on September 17, 2018.

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<sup>8</sup> As discussed below, Dr. Callaghan and Dr. Tornatore disagree about the reliability of tests performed by Therapath.



To assist the parties in producing helpful reports from experts, a set of instructions were issued in final form on August 9, 2019. For various reasons, Mr. Brantley's submission of a report was delayed. Eventually, Mr. Brantley presented a report from Dr. Tornatore on August 17, 2020. Exhibit 24.

After the first expert report, other reports followed. The Secretary submitted a report from Dr. Callaghan. Exhibit A. Dr. Tornatore responded. Exhibit 39 (dated Apr. 27, 2021). Dr. Callaghan responded for a second time. Exhibit C (dated July 12, 2021). Dr. Tornatore wrote a third report. Exhibit 41. Dr. Callaghan also wrote a third report. Exhibit D. This report concluded the phase in which experts disclosed their opinions.

The parties were instructed to file briefs regarding Mr. Brantley's entitlement to compensation as well as any possible award of pain and suffering. Order, issued Jan. 20, 2022. The parties submitted those briefs. With the submission of Mr. Brantley's reply brief, the case is ready for adjudication.

### **III. Standards for Adjudication**

A petitioner is required to establish his case by a preponderance of the evidence. 42 U.S.C. § 300aa–13(1)(a). The preponderance of the evidence standard requires a “trier of fact to believe that the existence of a fact is more probable than its nonexistence before [he] may find in favor of the party who has the burden to persuade the judge of the fact's existence.” Moberly v. Sec’y of Health & Hum. Servs., 592 F.3d 1315, 1322 n.2 (Fed. Cir. 2010) (citations omitted). Proof of medical certainty is not required. Bunting v. Sec’y of Health & Hum. Servs., 931 F.2d 867, 873 (Fed. Cir. 1991).

Distinguishing between “preponderant evidence” and “medical certainty” is important because a special master should not impose an evidentiary burden that is too high. Andreu v. Sec’y of Health & Hum. Servs., 569 F.3d 1367, 1379-80 (Fed. Cir. 2009) (reversing special master's decision that petitioners were not entitled to compensation); see also Lampe v. Sec’y of Health & Hum. Servs., 219 F.3d 1357 (Fed. Cir. 2000); Hodges v. Sec’y of Health & Hum. Servs., 9 F.3d 958, 961 (Fed. Cir. 1993) (disagreeing with dissenting judge's contention that the special master confused preponderance of the evidence with medical certainty).

#### IV. Diagnosis

In Broekelschen v. Sec’y of Health and Human Servs., 618 F.3d 1339, 1346 (Fed. Cir. 2010), the Federal Circuit recognized that in some circumstances, the special master may “first determine which injury was best supported by the evidence in the record before applying the Althen test.” Here, the appropriate diagnosis is one of the more disputed aspects. Dr. Tornatore asserts that the appropriate diagnosis is small fiber neuropathy. Exhibit 24 at 7. However, Dr. Callaghan disagrees. Exhibit A at 5.

##### A. Diagnostic Criteria

A substantial amount of disagreement appears to flow from a discrepancy in how the parties present the diagnostic criteria. Mr. Brantley maintains that small fiber neuropathy is an appropriate diagnosis. Citing the article by Devigili and others,<sup>9</sup> Mr. Brantley contends that a diagnosis of small fiber neuropathy “is based on clinical findings and the existence of an abnormal QST test or reduced nerve fiber density (IENFD) at the distal leg.” Pet’r’s Br. at 11. This decision refers to these criteria as the “inclusive criteria.” The Secretary agrees with the inclusive criteria. See Resp’t’s Br. at 14, citing Exhibit A (Dr. Callaghan’s report) at 5.

Mr. Brantley argues that “[n]o exclusion criteria were established because diagnosis based on clinical signs and specific diagnostic testing (QST or IENFD) was deemed reliable.” Pet’r’s Br. at 15. However, the Secretary adds a set of exclusionary criteria: “(i) any sign of large fiber impairment (light touch and/or vibratory and/or proprioceptive sensory loss and/or absent deep tendon reflexes); (ii) any sign of motor fiber impairment (muscle waste and/or weakness); (iii) any abnormality on sensorimotor NCS.” Resp’t’s Br. at 14, quoting Exhibit A at 5.

A close reading of the Devigili article supports the position taken by the Secretary and Dr. Callaghan. In 2019, a group of researchers from Milan, Italy assessed the diagnostic criteria for small fiber neuropathy. Previously, two sets of diagnostic criteria were used. The first set, known as the Besta criteria, featured a set of exclusion criteria. Devigili at 3729. The second set, which came from the Diabetic Neuropathy Study Group of the European Association for the Study of Diabetes, appears to have omitted any exclusion criteria. Id. Devigili and

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<sup>9</sup> Devigili et al., Diagnostic criteria for small fibre neuropathy in clinical practice and research, BRAIN: 142 A JOURNAL OF NEUROLOGY 3728 (2019), filed as Exhibit A, tab 1 [hereinafter Devigili].



colleagues compared the two sets of criteria via a re-appraisal of one cohort of sensory neuropathy patients and a prospective assessment of other patients. Id.

As part of the prospective assessment of patients, the researchers identified 342 patients who “met the entry criteria” and were not diagnosed with other conditions such as vascular stenosis. Id. at 3731. These patients underwent a series of tests. “The diagnostic classification was axonal large sensory fibre neuropathy (43; 12.6%), mixed large and small sensory fibre neuropathy [SFN] (81; 23.7%), sensory neuronopathy (16; 4.7%), demyelinating neuropathy (5; 1.5%), mononeuropathy (3; 0.8%), and multiplex mononeuropathy (7; 2%).” Id. The authors explained a point that is critical for Mr. Brantley’s claim that he suffered small fiber neuropathy: “The remaining 187 patients with no clinical and NCS evidence of large sensory and motor nerve fibre impairment were considered affected by possible SFN.” Id. In other words, the 155 patients with evidence of neuropathies involving large fibers were excluded from further study and considered not to have small fiber neuropathy. This process is presented graphically in Figure 1. Id. at 3733.

The Devigili article, thus, shows that researchers separate people with large fiber neuropathies from people with small fiber neuropathies. This article, by itself, is sufficient reason to reject the assertion that the diagnostic criteria for small fiber neuropathy does not contain any exclusion criteria.

However, if the issue were close (and it is not close), then Dr. Callaghan’s experience regarding small fiber neuropathy would tip the scales in his favor. Dr. Callaghan is board-certified in neurology and electrodiagnostic medicine. Exhibit B (curriculum vitae) at 1. He describes himself as a “neuromuscular specialist with a primary interest in patients with neuropathy including small fiber neuropathy.” Exhibit A at 1. Dr. Callaghan treats “approximately 100 patients with small fiber neuropathy each year.” Id.

By way of contrast, Dr. Tornatore is board-certified in neurology but not in electrodiagnostic medicine. See Exhibit 23 (curriculum vitae). Dr. Tornatore directs the Multiple Sclerosis Center at Georgetown University Medical Center, where he follows more than 3,000 patients with multiple sclerosis. Exhibit 24 at 2. But, this group includes only “18 patients with small fiber sensory neuropathy which is autoimmune in origin.” Id.

Thus, on the narrow question of whether small fiber neuropathy is an appropriate diagnosis, Dr. Callaghan’s background makes him more qualified than Dr. Tornatore. Although the Secretary asserted the difference in qualifications

elevates Dr. Callaghan over Dr. Tornatore (Resp't's Br. at 27), Mr. Brantley did not answer this argument. See Pet'r's Reply.

## **B. Mr. Brantley's Presentation**

As just discussed, the diagnostic criteria for small fiber neuropathy contains both inclusive criteria and exclusive criteria. Because exclusive criteria are more important in the context of this case, they are discussed first.

### **1. Exclusive Criteria**

Dr. Callaghan identifies exclusionary criteria as "(i) any sign of large fiber impairment (light touch and/or vibratory and/or proprioceptive sensory loss and/or absent deep tendon reflexes); (ii) any sign of motor fiber impairment (muscle waste and/or weakness); (iii) any abnormality on sensorimotor NCS." Exhibit A at 5. The basis for this list appears to be the Devigili article, although the Devigili article does not enumerate this specific list. See Devigili.

Relying upon Dr. Callaghan's opinion, the Secretary maintains that Mr. Brantley fulfilled all the exclusive criteria, meaning that Mr. Brantley did not suffer from small fiber neuropathy. Resp't's Br. at 14-15. These are taken up in sequence:

Any sign of large fiber impairment (light touch and/or vibratory and/or proprioceptive sensory loss and/or absent deep tendon reflexes). Dr. Pandey determined that Mr. Brantley had decreased vibration reflexes on December 8, 2015. Exhibit 1 at 58.

Any sign of motor fiber impairment (muscle waste and/or weakness). While Mr. Brantley was in the hospital, Dr. Pandey found a degree of weakness (4/5) of the left hip flexor, left knee extensor and left foot dorsal flexion. Exhibit 3 at 22-23 (Sep. 28, 2015). On October 13, 2015, Mr. Brantley told the neurosurgeon, Dr. Nguyen, that his current symptoms included muscle weakness, although weakness was not detected on examination. Exhibit 1 at 8. Dr. Pandey identified that Mr. Brantley had reduced strength in the left extensor hallucis. Exhibit 1 at 58 (Dec. 8, 2015).

Any abnormality on sensorimotor NCS. The results from the September 8, 2016 nerve conduction study included: "left median motor nerve showed decreased conduction velocity," "left median sensory nerve showed prolonged distal peak latency," and "left ulnar motor nerve showed reduced amplitude and decreased conduction velocity." Exhibit 10 at 41.

Based upon the above, Dr. Callaghan concluded that Mr. Brantley had “manifestations of large fiber nerve injury and not small fiber nerve injury.” Exhibit C at 2. Dr. Tornatore did not directly tackle this opinion. See Exhibit 41 (Dr. Tornatore’s third report).

At best, Mr. Brantley contends that he suffered from large fiber neuropathy as well as small fiber neuropathy. Pet’r’s Reply at 6. Although not cited in Mr. Brantley’s reply, Dr. Tornatore’s third report provides some lukewarm support for this proposition. See Exhibit 41 at 3 (“It is quite possible he [Mr. Brantley] had both”).

This position (large fiber neuropathy and small fiber neuropathy) is inconsistent with the Devigili methodology. As discussed above, patients with large fiber neuropathy were eliminated relatively early and were not even considered to have possible small fiber neuropathy. Devigili at 3731.

Accordingly, the Secretary and Dr. Callaghan have persuasively shown that Mr. Brantley displayed signs and symptoms of a large fiber neuropathy. Thus, the diagnosis of small fiber neuropathy is not appropriate.

## 2. Inclusive Criteria

To repeat, the “inclusive criteria” for small fiber neuropathy are: [1] clinical findings and [2] [a] the existence of an abnormal QST test or [b] reduced nerve fiber density at the distal leg. (Bracketed numbers and letters added). The parties have not cited any evidence showing Mr. Brantley had a QST test. However, he did have a skin biopsy, which could show reduced fiber density.

As alluded to earlier, the company, Therapath, evaluated the results of the skin biopsy. Exhibit 13 at 39. Although Therapath reported “significantly reduced epidermal nerve fiber density,” Dr. Callaghan contended that this report is suspect because Therapath has a high rate of false positives. Exhibit A at 5. For this proposition, Dr. Callaghan did not cite any literature. In his second report, Dr. Callaghan explained that the basis for his opinion is his experience in the field:

I do have experience with over 500 skin biopsies from research studies and personal experience using the Therapath company. I also frequently collaborate with the top skin biopsy laboratories in the world including the University of Rochester and the University of Utah. The consensus of the skin biopsy experts that I have

experience with is that Therapath often produces false positive results.

Exhibit C at 2.

In response, Dr. Tornatore made four points. Exhibit 41 at 3-4. He consulted the Therapath website and reported that Therapath is accredited by the Clinical Laboratory Improvement Amendments<sup>10</sup> and the College of American Pathologists' Laboratory Accreditation Program. Dr. Tornatore vouched for the qualifications of the neuropathologists who work for Therapath. Dr. Tornatore reasoned that the positive reports on three tests (as opposed to a single test) reduces the risk of a false positive. Finally, Dr. Tornatore pointed out that Dr. Thummala accepted the results of the biopsy.

The parties' arguments largely echo the opinions of the experts whom they retained. See Pet'r's Br. at 15-16; Resp't's Br. at 16-17; Pet'r's Reply at 7. To Dr. Callaghan's opinions, the Secretary added that Dr. Tornatore did not say that he, personally, uses Therapath.

Preliminarily, the idea that a test may produce false negatives and/or false positives is hardly surprising. Cases from the Vaccine Program have occasionally involved discussions about false negatives and/or false positives. See, e.g., Snyder v. Sec'y of Health & Hum. Servs., No. 01-162V, 2009 WL 332044, at \*111-15, \*123-24 (Fed. Cl. Spec. Mstr. Feb. 12, 2009), mot. for rev. denied, 88 Fed. Cl. 706 (2009); Dela Rosa v. Sec'y of Health & Hum. Servs., No. 93-433V, 2001 WL 1056928, at \*18 (Fed. Cl. Spec. Mstr. Aug. 14, 2001).

The more important question is whether any evidence shows that Mr. Brantley's skin biopsy results constitute a false positive. In this regard, the reputation of Therapath might contribute to this answer. See Giannantonio v. Sec'y of Health & Hum. Servs., No. 18-497V, 2023 WL 2721387, at \*8 (Fed. Cl. Spec. Mstr. Feb. 1, 2023), mot. for rev. denied, 2023 WL 6629897 (Fed. Cl. Aug. 3, 2023).

Additional evidence would be helpful. For example, the Secretary might have obtained affidavits from laboratorians at the University of Rochester and the University of Utah, who apparently share Dr. Callaghan's view about Therapath. Mr. Brantley could have presented evidence showing how the accreditation process for laboratories minimizes the risk of false positives. Dr. Tornatore could have

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<sup>10</sup> Dr. Tornatore stated that "Therapath is CLIA accredited." However, Therapath's website actually states that "Therapath is licensed under CLIA."

testified about his experience (or lack thereof) with using Therapath. Ultimately, the best evidence about the reliability of the results of Mr. Brantley's August 2017 skin biopsy might be to obtain another biopsy.

Ultimately, determining the reliability of the results from Mr. Brantley's skin biopsy and soliciting more evidence on this topic are unnecessary. If Mr. Brantley's skin biopsy were reliable, then the presence of exclusionary factors, as explained above, still makes the diagnosis untenable.<sup>11</sup>

### C. Treating Doctors

On the topic of diagnosis, the opinions of treating doctors can be quite probative. Cappizano v. Sec'y of Health & Hum. Servs., 440 F.3d 1317, 1326 (Fed. Cir. 2006). The views of treating doctors about the appropriate diagnosis are often persuasive because the doctors have direct experience with the patient whom they are diagnosing. See McCulloch v. Sec'y of Health & Hum. Servs., No. 09-293V, 2015 WL 3640610, at \*20 (Fed. Cl. Spec. Mstr. May 22, 2015). However, the views of a treating doctor are not absolute, Snyder v. Sec'y of Health & Hum. Servs., 88 Fed. Cl. 706, 745 n.67 (2009), even on the question of diagnosis, R.V. v. Sec'y of Health & Hum. Servs., 127 Fed. Cl. 136, 141 (2016), appeal dismissed, No. 16-2400 (Fed. Cir. Oct. 26, 2016).

Here, Mr. Brantley argues: "Mr. Brantley objectively meets the diagnostic criteria for small fiber neuropathy and was properly diagnosed with small fiber neuropathy by his treating neurologist." Pet'r's Br. at 9. Mr. Brantley did not identify the treating neurologist who diagnosed him with small fiber neuropathy. See id. Mr. Brantley later maintains "both his treating neurologists, Dr. Pand[e]y and Dr. Thummala, diagnosed him with SFN." Pet'r's Reply at 5. However, Mr. Brantley did not cite a medical record (exhibit number, page number) that supports this statement.

After Dr. Thummala received the results from Therapath about the skin biopsy, Dr. Thummala assessed Mr. Brantley as having "Pain in lower limb – possible small fiber neuropathy." Exhibit 13 at 4. But, a treater's statement that a particular condition is possible does not require a special master to accept that

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<sup>11</sup> If the reliability of the skin biopsy were critical to the outcome, then the undersigned would likely have convened a hearing to ask Dr. Tornatore and Dr. Callaghan questions. Without any additional testimony, the undersigned tentatively finds that the Secretary has not rebutted the presumption of accuracy afforded to medical testing from an accredited laboratory.

diagnosis. Hibbard v. Sec’y of Health & Hum. Servs., 698 F.3d 1355, 1364-65 (Fed. Cir. 2012).

#### **D. Summary regarding Diagnosis**

The evidence regarding diagnosis is mixed. Mr. Brantley may legitimately point to some evidence regarding a diagnosis of small fiber neuropathy. For example, Dr. Thummala wrote that small fiber neuropathy is “possible.” In addition, Mr. Brantley retained a neurologist (Dr. Tornatore) whose theory of the case includes an assertion that Mr. Brantley suffered from small fiber neuropathy. However, the stronger evidence supports a finding that Mr. Brantley has not established the small fiber neuropathy diagnosis with preponderant evidence. On the topic of diagnosing small fiber neuropathy, Dr. Tornatore is less qualified than the neurologist whom the Secretary retained, Dr. Callaghan. Dr. Callaghan’s explanation of the diagnostic criteria was sound and reliable. The diagnostic criteria support Dr. Callaghan’s opinion that small fiber neuropathy is not an appropriate diagnosis for Mr. Brantley.

Without persuasive proof that Mr. Brantley suffers from small fiber neuropathy, there is no reason to explore whether any vaccine was the cause-in-fact of a hypothetical small fiber neuropathy. “In the absence of a showing of the very existence of any specific injury of which the petitioner complains, the question of causation is not reached.” Lombardi v. Sec’y of Health & Hum. Servs., 656 F.3d 1343, 1353 (Fed. Cir. 2011).

#### **V. A Hearing Is Not Required**

Special masters possess discretion to decide whether an evidentiary hearing will be held. 42 U.S.C. § 300aa-12(d)(3)(B)(v) (promulgated as Vaccine Rule 8(c) & (d)), which was cited by the Federal Circuit in Kreizenbeck v. Sec’y of Health & Hum. Servs., 945 F.3d 1362, 1365 (Fed. Cir. 2018).

Mr. Brantley has had a fair and full opportunity to present his case. Dr. Tornatore and Dr. Callaghan each wrote three reports. Throughout the pendency of the case, Mr. Brantley was provided multiple opportunities to present expert reports to show that the flu vaccination harmed him. The parties also submitted briefs to focus their arguments on the critical elements, including whether Mr. Brantley suffered from small fiber neuropathy. A hearing is not needed to resolve this issue.



## **VI. Conclusion**

After his vaccination Mr. Brantley experienced health problems, for which he merits sympathy. However, he has not established a fundamental element of his case, namely, that he suffers from the condition that he alleges a vaccine caused. His claim for compensation is, therefore, denied.

The Clerk's Office is instructed to enter judgment in accord with this decision unless a motion for review is filed. Information about filing a motion for review, including the deadline, can be found in the Vaccine Rules, which are available on the website for the Court of Federal Claims.

**IT IS SO ORDERED.**

s/Christian J. Moran  
Christian J. Moran  
Special Master